

## A1.11 Should antagonist pharmacotherapy, naltrexone, be used for the treatment of opioid dependence?

### GRADE evidence profile

**Author(s):** Minozzi, Amato  
**Date:** 23/03/2006  
**Question:** Should oral naltrexone be used for opioid dependence?  
**Patient or population:** Opioid-dependent patients  
**Settings:** Outpatient  
**Systematic review:** Minozzi et al.; *Oral naltrexone treatment for opioid dependence* (CLIB 1, 2006)<sup>[170]</sup>.

| Quality assessment   |                   |                                       |                            |   |  | Summary of findings |                |                                     |  |      | Quality  | Importance |
|--|-------------------|---------------------------------------|----------------------------|---|--|---------------------|----------------|-------------------------------------|--|------|----------|------------|
| No. studies  | Design            | Limitations                           | Consistency                | Directness                                | Other considerations                       | No of patients      |                | Effect                              |  |      |          |            |
|  |                   |                                       |                            |   |  | Oral naltrexone     | Placebo        | Relative risk (RR) (95% CI)         | Absolute risk (AR) (95% CI)            |      |          |            |
| <b>Retention in treatment</b> <sup>[239, 240, 241, 242, 243]</sup> (Objective follow-up: 2-9 months <sup>d</sup> )           |                   |                                       |                            |   |  |                     |                |                                     |  |      |          |            |
| 5 <sup>a</sup>   | Randomized trials | No limitations <sup>b</sup>           | No important inconsistency | No uncertainty                            | Imprecise or sparse data (-1)              | 35/105 (33,3%)      | 31/98 (31,6%)  | RR 1.08 <sup>e</sup> (0.74 to 1.57) | 20/1 000 more (90 less to 140 more)    | ⊕⊕⊕○ | Moderate | 6          |
| <b>Use of opioids</b> <sup>[239, 244, 240, 241, 242, 243]</sup> (Objective <sup>e</sup> follow-up: 2-9 months <sup>d</sup> ) |                   |                                       |                            |   |  |                     |                |                                     |  |      |          |            |
| 6 <sup>a</sup>   | Randomized trials | Serious limitations (-1) <sup>b</sup> | No important inconsistency | No uncertainty                            | Imprecise or sparse data (-1)              | 68/139 (48,9%)      | 69/110 (62,7%) | RR 0.72 <sup>e</sup> (0.58 to 0.90) | 180 less / 1 000 (290 less to 60 less) | ⊕⊕○○ | Low      | 7          |
| <b>Relapsed at follow-up</b> <sup>[241, 242]</sup> (follow-up: 6 months-1 year)  |                   |                                       |                            |   |  |                     |                |                                     |  |      |          |            |
| 2 <sup>b</sup>   | Randomized trials | No limitations <sup>b</sup>           | No important inconsistency | No uncertainty                            | Imprecise or sparse data (-2) <sup>i</sup> | 26/43 (60,5%)       | 24/38 (63,2%)  | RR 0.94 <sup>e</sup> (0.67 to 1.34) | 40 less / 1 000 (250 less to 180 more) | ⊕⊕○○ | Low      | 7          |
| <b>Criminal behaviour</b> <sup>[245, 246]</sup> (objective <sup>e</sup> follow-up: 6-10 months <sup>d</sup> )                |                   |                                       |                            |   |  |                     |                |                                     |  |      |          |            |
| 2 <sup>b</sup>   | Randomized trials | No limitations <sup>b</sup>           | No important inconsistency | Specific population (prison release) (-1) | Imprecise or sparse data (-2)              | 13/54 (24,1%)       | 15/32 (46,9%)  | RR 0.50 <sup>e</sup> (0.27 to 0.91) | 240 less / 1 000 (440 less to 30 less) | ⊕○○○ | Very low | 6          |

- <sup>a</sup> Outpatient. Country of origin: Israel 2, USA 1, Russia 1, Spain 1  
<sup>b</sup> 2 adequate allocation concealment, the other unclear; all double blind  
<sup>c</sup> Fixed effect model  
<sup>d</sup> Length of treatment  
<sup>e</sup> All outpatient. Country of origin: Israel 2, USA 1, China 1, Russia 1, Spain 1  
<sup>f</sup> Based on urinalysis  
<sup>g</sup> 2 adequate allocation concealment, the other unclear; all double blind. ITT analyses not used.  
<sup>h</sup> Both outpatient, one conducted in Israel, the other in Spain  
<sup>i</sup> 1 with adequate allocation concealment, 1 unclear, both double blind  
<sup>j</sup> Few patients, result not statistically significant  
<sup>k</sup> All outpatient, conducted in USA, China and Russia 1 each  
<sup>l</sup> 1 adequate allocation concealment, 2 unclear, all double blind  
<sup>m</sup> Number of subjects with at least one side effect  
<sup>n</sup> Both outpatient and both conducted in USA  
<sup>o</sup> Number re-incarcerated  
<sup>p</sup> Both unclear allocation concealment and open design  
<sup>q</sup> 2 studies, few patients